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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/526,379	03/16/2000	Lecon Woo	1417Y P 418	2449

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EXAMINER

NOLAN, SANDRA M

ART UNIT

PAPER NUMBER

1772

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/526,379

Applicant(s)

WOO ET AL.

Examiner

Sandra M. Nolan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-33 and 35-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-33 and 35-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>17</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 April 2002 (Paper No. 16) has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 21 April 2003 (Paper No. 17) was considered by the examiner.

Pending Claims

3. Claims 1-1, 13-33 and 35-41 are pending.

Rejections Withdrawn

4. The 35 USC 103 rejection of claims 1-2, 13, 16-22, 24 and 38-44, as unpatentable over Barney et al (US 6,203,535) in view of Galante (US 5,272,210), as rested in section 4 of the 27 January 2003 office action (Paper No. 13), is withdrawn.

5. The 35 USC 103 rejection of claim 23 as unpatentable over Barney and Galante and further in view of Occhiello et al (EPO 0423499), as repeated in section 5 of Paper No. 13, is withdrawn.

6. The 35 USC 103 rejection of claims 1, 2, 4-8, 13-24, 26-30 and 36-44 as obvious over Barney in view of Wilhoit et al (US 5,928,740), as restated in section 6 of Paper No. 13, is withdrawn.

7. The 35 USC rejection of claims 9-11, 31-33 and 35 as unpatentable over Barney and Wilhoit in view of Sudo (EPO 05506034), as repeated in section 7 of Paper No. 13, is withdrawn.

New Rejections

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 7-25 and 38-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenbaum et al (WO 95/13918).

Rosenbaum teaches medical grade containers (page 1, lines 1-4, page 15, line 2, Figure 10) made with laminated films that contain an RF-susceptible layer comprising a blend of an ultra low density polyethylene (ULDPE) (page 10, line 21; claim 3 of the publication) and a propylene-based component (abstract; claim 2 of the publication) that is preferably an ethylene/propylene copolymer containing 2 to 6% ethylene (page 10, lines 9-16). The properties of the films used in applicants' containers are recited at page 5, lines 12-34.

The use of radiation to treat the containers (per applicants' claims 16 and 21) is deemed a process limitation and does not affect the patentability of the containers themselves.

The design features of the container (per applicants' claims 17-20 and 38-41) do not affect the patentability of the films used in the containers.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 9-11 and 31-33 are rejected under 35 U.S.C. 103(a) as being obvious over Rosenbaum in view of Sudo (EPO 0556034 A1).

Rosenbaum is discussed above. It fails to teach the claimed cyclic olefin copolymers.

Sudo teaches blood bags (page 3, lines 5-6 and Figure 9) made of copolymers of propylene (page 7, line 56 through page 8, line 2) with cyclic olefins having single- and

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bridged-ring structures (page 3, line 46 through page 7, line 55). The copolymers can be used in admixture with other olefin resins (page 3, line 24) and have superior properties, including chemical resistance (page 3, lines 38-44).

The references are analogous because they both deal with olefinic copolymers and their use in making medical containers.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the cyclic olefins of Sudo in place of the ethylene/propylene copolymer component of Rosenbaum in its films in order to make containers having superior chemical resistance.

The motivation to employ the Sudo copolymers in the Rosenbaum films is found at page 3, line 24 and at page 3, lines 38-44 of Sudo, where mixtures of the Sudo copolymers with other olefinic polymers and the chemical resistance of the Sudo copolymers are discussed.

It is deemed desirable to make medical containers having good chemical resistance in order to insure that the containers will not interact with their contents or with other reagents with which they come in contact during storage or use.

13. Claims 4-8, 13-16, 21, 26-30 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenbaum in view of Wilhoit et al (US 5,928,740).

Rosenbaum is discussed above. It fails to teach the use of two copolymers in its propylene-based component.

Wilhoit teaches films having heat sealing and puncture resistance properties (abstract) that contain a blend (abstract) of single-site catalyzed ethylene/C3-10 olefin

copolymer (col. 7, lines 24-38) and ethylene/C3-10 olefin copolymer (col. 7, lines 59-63). The films can be crosslinked with 1 to 10 Mrad of radiation (col. 10, lines 22-24).

The references are analogous because they deal with olefinic films.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the blended copolymers of Wilhoit as the propylene-based component in the films of Rosenbaum in order to improve the heat sealing and puncture resistance of medical containers made therefrom.

The motivation to employ the blends of Wilhoit in the films of Rosenbaum is found in the Wilhoit abstract, where the heat sealing and puncture resistance properties of its blends are taught.

It is deemed desirable to make medical containers that have heat sealability in order to facilitate production of the containers and/or their connection to other medical equipment, such as tubing.

It is deemed desirable to make medical containers that are puncture resistant in order to minimize the production of potentially hazardous leaks during the transportation and storage of biological fluids.

Radiation crosslinking is deemed a process limitation that does not distinguish the claimed films from others not so treated. Nonetheless, the use of suitable levels and types of radiation to crosslink the containers suggested by the combination of Rosenbaum and Wilhoit is deemed a matter of engineering choice.

Conclusion

Any inquiry concerning this communication should be directed to the Examiner, Sandra M. Nolan, whose telephone number is 703/308-9545. The Examiner can normally be reached on Monday through Thursday, from 6:30 am to 4:00 pm, Eastern Time.

If attempts to reach the Examiner by telephone are unsuccessful, her supervisor, Harold Pyon, can be reached at 703/308-4251. The general fax number for the art unit is 703/305-5436. The fax number for after final communications is 703/872-9310. The receptionist answers 703/308-0661.



S. M. Nolan
Patent Examiner
Technology Center 1700

SMN/smn
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